

## REMARKS

The final Office Action was issued on claims 12 and 18-35. Claims 12, 18-31, 34, and 35 were rejected and claims 22, 32, and 33 were objected to. In this Response, claims 12, 18, 20-25, 29, and 31 have been amended, no claims have been cancelled, and claims 36-48 have been added. Thus, claims 12 and 18-48 are pending in the application.

### **Claim Amendments**

In this Response, claims 12, 18, 20-25, 29, and 31 have been amended. The amendments have been made to clarify the claims and to remove means-plus-function claim format. Although Applicants believe that the claims were allowable without the amendments, the claims have been clarified to place the claims in better form for allowance. Applicants submit that the claims have not been narrowed and subject matter has not been surrendered.

### **Allowable Subject Matter**

At page 5 of the Office Action, claims 22, 32, and 33 were objected to as being dependent upon a rejected base claim, but noted as being allowable if rewritten in independent form including all the limitation of the base claim and any intervening claims. Also at page 5 of the Office Action, claims 21 and 31 were noted as being allowable if rewritten to overcome the rejections under 35 U.S.C. § 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims. Applicants thank the Examiner for the notice of allowable claims.

In response, claims 36-40 have been added. Claim 36 corresponds to claim 21 rewritten in independent form and to overcome the § 112, second paragraph, rejection. Claim 37 corresponds to claim 22 rewritten in independent form. Claim 38 corresponds to claim 31 rewritten in independent form and to overcome the § 112, second paragraph, rejection. Claim 39 corresponds to claim 32 rewritten in independent form. Claim 40 corresponds to claim 33 rewritten in independent form.

Accordingly, Applicants respectfully submit that claims 36-40 are allowable.

### Claim Objections

At page 2 of the Office Action, claim 24 was objected to as containing an informality. Claim 24 has been amended and Applicants submit that the objection to claim 24 has been overcome.

### Claim Rejections – 35 USC §112

At page 2 of the Office Action, claims 21, 24-26, 31, and 34-35 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Regarding claims 21 and 31, claims 21 and 31 have been amended to clarify the claims. Regarding claims 24-26 and 34-35, claims 24 and 25 have been amended to clarify the claims. Independent claims 18 and 29 have also been amended to clarify the claims. As to the perimeters of the flexible container and the box, a substantially horizontal cross-sectional plane through the container and the box when the container is positioned within the box defines the perimeters of the container and the box.

Applicants respectfully submit that the amendments to the claims do not narrow the claims or surrender any subject matter. Furthermore, the amendments are not made for substantial reasons related to patentability.

Applicants submit that the § 112, second paragraph, rejection has been overcome.

### Claim Rejections – 35 USC §102

At Office Action pages 2 and 3, claims 12 and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Mackiewicz et al. (UK 2,121,467 A). Claims 18, 24, 25, 27, and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cox, Jr. (US 3,117,695). Applicants respectfully disagree.

Regarding claim 12, claim 12 has been amended to clarify the claim. Claim 12 defines the large volume flexible medical container as having a top side having a top outer perimeter edge. A container hanger is connected to a top portion of the top side of the flexible container spaced inward from the top outer perimeter edge. The container hanger applies an upward force to the portion of the flexible container.

One example of Applicants' invention, as claimed in claim 12, is shown in Fig. 13. The large volume flexible medical container has a top side which has a top outer perimeter edge (see also the container 10 in Fig. 1). A container hanger (150) is connected to a portion of the top side of the flexible container at a location spaced inward from the top outer perimeter edge. The container hanger (150) applies an upward force to the portion of the flexible container. The reference to Fig. 13 is merely for an example of Applicants' invention and is not intended to limit the claims.

Turning to Mackiewicz et al., a silo (2) is suspended from a supporting frame (1). More particularly, the silo (2) is suspended from the supporting frame (1) at upper edges (3) of the silo (2). See Fig. 1 of Mackiewicz et al. Mackiewicz et al. does not have a container hanger connected to a top portion of the silo (2) spaced inward from the upper edges 3. Furthermore, the silo (2) is merely suspended from the supporting frame (1). Mackiewicz et al. does not provide a container hanger which applies an upward force to a top portion of the silo (2).

Applicants' invention can provide advantages over Mackiewicz et al. Because Applicants' container hanger is connected to a top portion of the large volume flexible container at a location spaced inward from a top outer perimeter edge, Applicants' container provides for improved emptying and filling of the container. For example, as the container is filled the hanger system permits full deployment of the flexible container along the contours of the box. Undesirable pleating of the container during filling is minimized. Applicants' invention reduces extreme stresses otherwise placed on container seams which can cause seam failure, leakage, or contamination of the medical fluid contents inside of the container. Furthermore, the upward force applied to the container by the container hanger improves the draining process of the container. For example, as Applicants' container is drained, inward folding pleats of the container are defined. This allows Applicants' container to be refilled in an advantageous manner that properly deploys the container within the box and again reduces stresses on container seams. See Applicants' specification at pages 15-17 and Figs. 17a-e.

Conversely, Mackiewicz et al. shows in Fig. 4 the silo (2) being emptied in a manner quite different from Applicants' invention. Accordingly, Mackiewicz et al. does not provide the above advantages of Applicants' invention.

As to claim 18, claim 18 has been amended to clarify the claim. Claim 18 defines the flexible container as having a volume of at least about 200 liters. Furthermore, the flexible

container has a first perimeter defined by a substantially horizontal cross-sectional plane. The box has a second perimeter also defined by the substantially horizontal cross-sectional plane. The first perimeter of the flexible container is greater than the second perimeter of the box.

One example of Applicants' claimed invention is shown in Figs. 22-25 and described in the specification at page 17. Figure 22 shows a plan view looking downward at the flexible container positioned within the box in cross-section by a substantially horizontal plane. A perimeter P1 of the container is greater than a perimeter P2 of the box. The reference to the figures is merely for an example of Applicants' invention and is not intended to limit the claims.

Turning to Cox Jr., Cox Jr. pertains to a fluid dispensing container such as for milk, ice cream mix, and the like. Cox, Jr. does not disclose or suggest a flexible container having a volume of at least about 200 liters. Furthermore, Cox, Jr. does not disclose or suggest that a horizontal cross-section plane through the plastic bag or liner (19) and the outer shell (10) defines perimeters as claimed in Applicants' claim 18. Specifically, Cox, Jr. does not disclose or suggest that the perimeter of the plastic bag (19) be greater than the perimeter of the outer shell (10). The wrinkles referred to in the Office Action and apparently shown in the plastic bag (19) of Fig. 1 of Cox, Jr. are not described by Cox, Jr. and are apparently merely wrinkles. Nowhere does Cox, Jr. describe the plastic bag (19) as being larger in cross-section than the outer shell (10). Furthermore, Cox, Jr. does not describe a problem with flexible containers being smaller than their outer shells or any advantages to providing a flexible container that is larger than its outer shell.

Applicants' invention, on the other hand, provides advantages for flexible containers having a volume of at least about 200 liters. Applicants' invention provides for improved deployment of the flexible container within the box such that undesirable stresses on the flexible container, particularly container seams, are reduced. Flexible containers containing liquid, for example at least about 200 liters of liquid, can be subject to intense stresses on the walls of the container and the seams of the container. Such intense stresses can result in failure of the container which may cause leakage of the fluid or contamination of the fluid.

As to claims 20, 24, 25, 27, and 28, those claims are allowable at least for the reasons that there respective independent claims are allowable. Thus, Applicants respectfully submit that the §102 (b) rejections have been overcome.

**Claim Rejections-35 U.S.C. §103**

At Office Action pages 3-5, claims 19 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cox, Jr. Claims 29, 30, 34, and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cox, Jr. Claim 23 was rejected under 35 U.S.C. §103(a) as being unpatentable over Mackiewicz et al. in view of Love (US 4,306,668). Applicants respectfully disagree.

Regarding independent claim 29, claim 29 has been amended to clarify the claim. Particularly, the container hanger connected to the top portion of the large-volume flexible container applies an upward force to the top portion of the large-volume flexible container. Claim 29 also calls for the large-volume flexible container to have a size greater than the interior volume of the box.

Turning to Cox, Jr., Applicants submit Cox, Jr. does not disclose or suggest a container hanger connected to a top portion of a large-volume flexible container which applies an upward force to the top portion of the container. The Office Action asserts that Cox, Jr. has a hanger (17) connected to a top portion (23) of a bag (19). However, Figure 6 of Cox, Jr. shows the flap (17) as being at a bottom of the bag (19) during use. Fig. 1 of Cox, Jr. shows the container in a storage or transport position which is upside down relative to the use position shown in Fig. 6. The flap (17) is flexible to permit the flap (17) to be deformed as described in Cox, Jr. at column 2, lines 57-62. Accordingly, the Cox, Jr. flap (17) is not a container hanger connected to a top portion of the flexible container. Furthermore, the flexible flap (17) does not apply an upward force to a top portion of the bag (19).

Furthermore, Applicants' invention, as claimed in claim 29, calls for the large-volume flexible container to have a size greater than the interior volume of the box. Referring to the remarks above regarding claim 18 in view of Cox, Jr., Applicants submit that Cox, Jr. does not disclose or suggest that the plastic bag (19) have a greater volume than the outer shell (10). For example, Cox, Jr. does not describe the apparent wrinkles shown in Fig. 1 of the plastic bag (19) containing milk as an express or implied disclosure of the milk containing bag (19) being larger in volume than the outer shell (10). Furthermore, milk dispensing containers according to Cox, Jr. would not be subject to the same intense fluid generated stresses on the bag as compared to Applicants' large-volume flexible container. Accordingly, there would be no motivation for one

of ordinary skill in the art to modify the plastic bag of Cox, Jr. to be larger than the outer shell to address the problems with filling large-volume flexible containers.

As to dependents claims 19, 23, 26, 30, 34, and 35, those claims are allowable at least for the same reasons that their respective independent claims are allowable.

Thus, Applicants respectfully submit that the §103 rejections have been overcome.

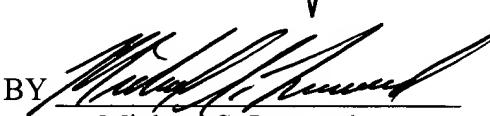
### **CONCLUSION**

For the foregoing reasons, Applicants submit that the patent application is in condition for allowance and request a Notice of Allowance be issued.

Respectfully submitted,

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